IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION

Master Docket: Misc. No. 21-1230

MDL No. 3014

SENIOR JUDGE JOY FLOWERS CONTI

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THIS DOCUMENT RELATES TO:

JOHN K. KRAVETZ

and

JANET KRAVETZ

Plaintiffs,

v.

KONINKELIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; and PHILIPS RS NORTH AMERICA LLC,

Defendants.

COMPLAINT FOR DAMAGES
JURY TRIAL DEMANDED

Plaintiffs John Kravetz and Janet Kravetz, by and through their undersigned counsel, hereby submit the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"), Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("PHUSA"), and Philips RS North America LLC ("Philips RS") (collectively referred to as "Philips" or the "Defendants") and allege the following upon personal knowledge and belief, and investigation of counsel:

INTRODUCTION

1. Philips manufactures, markets, sells, and distributes a variety of products for sleep

and home respiratory care.

2. Phillips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiLevel PAP) devices for patients with obstructive sleep apnea ("OSA").

3. Philips also manufactures, markets, imports, sells, and distributes a variety of ventilator devices for patients with respiratory conditions.

4. On April 26, 2021, Philips made a public announcement disclosing it had determined there were risks that the PE-PUR Foam used in certain CPAP, Bi-Level PAP, and mechanical ventilator devices it manufactured may degrade or off-gas under certain circumstances.[1]

5. On June 14, 2021, Royal Philips issued a recall in the United States of its CPAP, Bi-Level PAP, and mechanical ventilator devices containing PE-PUR Foam, because Philips had determined that (a) the PE-PUR Foam was at risk for degradation into particles that may enter the devices' pathway and be ingested or inhaled by users, and (b) the PE-PUR Foam may off-gas certain chemicals during operation.[1] Philips further disclosed in its Recall Notice that "these issues can result in serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment."[2]

6. Philips has disclosed that the absence of visible particles in the devices does not mean that PE-PUR Foam breakdown has not already begun. Philips reported that lab analysis of the degraded foam reveals the presence of harmful chemicals, including: Toluene Diamine

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[1] *See* Philips Recall Notice at https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/philips-recall-letter-2021-11-16-a-cpap-a-ventilator-recall-letter-us-revised.pdf?_gl=1*o6lnyn*_ga*OTk3Mjg3MDU0LjE2NDEzNjEyMTg.*_ga_2NMXNNS6LE*MTY0MTM2MTIxOC4xLjEuMTY0MTM2MTIyOC42MA..*_fplc*MGkyYjA4dzJZJTJCVXlTT0pJcVg5aHJFN0owYWN2QktaeFl0aGNOczRYN3J0c2RrdHlzRUhJV1dNb1g0Z2YyUTdnNGRPb0s0VlZMdTFwJTJGNTdkJTJCWTBiMHhDS1hDRnRoN2NVYVZnZjZsMFJXN1JaWWhmcUh1SEJxejgweW03SUVRJTNEJTNE*_ga_Q243QQ1P76*MTY0MTM2MTIxOC4xLjEuMTY0MTM2MTIyOC42MA..&_ga=2.130547343.1494262035.1641361218-997287054.1641361218.

[2] Id.

("TDA"), Toluene Diisocyanate ("TDI"), and Diethylene Glycol ("DEG").[3]

7. Prior to issuing the Recall Notice, Philips received complaints regarding the presence of black debris/particles within the airpath circuit of its devices (extending from the device outlet, humidifier, tubing, and mask). Philips also received reports of headaches, upper airway irritation, cough, chest pressure and sinus infection from users of these devices.

8. In its Recall Notice, Philips disclosed that the potential risks of particulate exposure to users of these devices include: irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (*e.g.*, kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing of PE-PUR Foam in these devices include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects, including lung diseases, cancer and possibly death.

9. Philips recommended that patients using the recalled CPAP and Bi-Level PAP devices immediately discontinue using their devices and that patients using the recalled ventilators for life-sustaining therapy consult with their physicians regarding alternative ventilator options. Philips further recommended that patients stop using ozone-related cleaning products.

10. In or around October 2020, Plaintiff was diagnosed with obstructive sleep apnea due to breathing difficulties by Dr. John Florinio in Middlefield, Ohio and was prescribed a Philips Dream Station machine with a nasal mask for sleeping. Plaintiff rented a Philips Dream Station from a durable medical equipment provider in Middlefield, Ohio in or around October 2020.

12. In or around August 2021, Plaintiff saw that Philips had issued a recall and determined that he may have a device that was subject to this recall Plaintiff registered his Philips device's serial number on Defendants' website found at:

[3] Philips Sleep and Respiratory Care Update; Clinical information for physicians, https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/information-forphysicians-and-providers (accessed July 19, 2021).

https://www.philipssrcupdate.expertinquiry.com/registration?ulang=en and confirmed the Philips Dream Station was subject to the recall.

13. Plaintiff John Kravetz was prescribed the use of a Philips Dream Station and rented the Philips recalled device (hereinafter the "subject device").

14. Plaintiff was diagnosed with having increased difficulty breathing, headaches, dizziness, extreme nausea, and loss of balance (falling) in August 2021 following the prolonged use of the Recalled Device and has been under the care of his primary physician for such diagnoses since that time without improvement.

15. As a direct and proximate result of Philips' conduct, Plaintiff has suffered serious and substantial life-altering injuries.

16. As a direct and proximate result of the subject device that was manufactured, marketed, imported, sold, and distributed by Philips, Plaintiff has suffered physical, emotional, and financial injuries, including but not limited to coughing, wheezing, and upper respiratory infections, among other injuries.

THE PARTIES

17. Plaintiffs John Kravetz and Janet Kravetz are residents and citizens of Geauga County, Ohio.

18. Following his obstructive sleep apnea diagnosis in October 2020, Plaintiff began using the Philips Dream Station on a nightly basis. Plaintiff used the subject device for approximately two years prior to being diagnosed with increased difficulty breathing, headaches, dizziness, extreme nausea, and loss of balance (falling).

19. Defendant Koninklijke Philips N.V. ("Royal Philips") is a public limited liability company established under the laws of The Netherlands, having its principal executive offices at

Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the parent company of the Philips Group of healthcare technology businesses, including Connected Care businesses focusing on Sleep & Respiratory Care. Royal Philips holds directly or indirectly 100% of its subsidiaries Philips NA and Philips RS.[4] Upon information and belief, Royal Philips controls Philips NA and Philips RS in the manufacturing, selling, distributing, and supplying of the recalled CPAP, Bi-Level PAP, and mechanical ventilator devices.[5] Royal Philips can be served with process via the *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters* ("Hague Service Convention").

22. Defendant Philips North America LLC ("Philips NA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141.

23. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA.

24. Defendant Philips RS North America LLC ("Philips RS") is a Delaware corporation with its principal place of business located at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is a wholly- owned subsidiary of Royal Philips. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips

[4] Philips 2020 annual filing with the SEC, fn. 8, https://www.sec.gov/Archives/edgar/data/313216/000031321621000008/phg-exhibit8.htm (accessed July 20, 2021).

[5] Philips 2020 annual filing with the SEC, https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm (accessed July 20, 2021).

acquired Respironics in 2008.

25. Royal Philips, Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

JURISDICTION AND VENUE

26. This Court has diversity subject matter jurisdiction under 28 U.S.C. §1332, because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00.

27. Specifically, as alleged herein, Plaintiff is a citizen of the State of Ohio and Defendants are citizens of: the Kingdom of the Netherlands and the States of Delaware, Massachusetts, and Pennsylvania.

28. Additionally, the damages Plaintiff sustained as a result of Defendants' researching, developing, designing, manufacturing, selling, distributing, and marketing of the subject devices, and failure to warn of their serious and life-threatening risks, substantially exceeds $75,000.00.

29. United States District Court, District of Massachusetts has specific personal jurisdiction over Defendants, because Defendants regularly transact business in Massachusetts by engaging in the researching, developing, designing, manufacturing, selling, distributing, and marketing of, amongst other products, BiPAP/CPAP and ventilator devices, including the subject devices, in Massachusetts.

30. Defendants derive substantial revenue from their business transactions in Massachusetts and have purposely availed themselves of the privilege of doing business in Massachusetts.

31. Furthermore, Philips NA and Philips Holding maintain their principal places of business in Massachusetts.

32. Defendants reasonably anticipated or should have reasonably anticipated being subjected to specific personal jurisdiction in this state as a result of their actions in researching, developing, designing, manufacturing, selling, distributing, and marketing, amongst other products, the recalled devices, including the subject devices, in Massachusetts.

33. Defendants have sufficient minimum contacts with Massachusetts such that subjecting them to specific personal jurisdiction in this state does not offend traditional notions of fair play and substantial justice and comports with due process.

34. Venue in the District of Massachusetts is proper because Philips NA and Philips Holding are headquartered and regularly conduct business in this District and because a substantial part of the events and omissions giving rise to the claim occurred in this District.

35. On October 8, 2021, pursuant to the Transfer Order of the Judicial Panel on Multidistrict Litigation, this action was transferred pursuant to 28 U.S.C. § 1407 to the Western District of Pennsylvania for coordinated pretrial proceedings in MDL 3014, IN RE: PHILIPS RECALLED CPAP, BI -LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATIONS.

36. Pursuant to this Court's Pre-Trial Order No. 1 (ECF No. 8), venue in the Western District of Pennsylvania is proper for pretrial purposes only and without any determination that the action should be consolidated for trial in this District.

FACTUAL BACKGROUND

38. At all relevant times, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep apnea.

39. Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Recalled Devices, including the subject devices used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

I. Continuous Positive Airway Pressure ("CPAP")

40. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a hose and a nasal or facemask device that delivers constant and steady air pressure to an individual's throat to help individuals breathe.

41. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

II. Bi-Level Positive Airway Pressure Therapy

42. Bi-Level Positive Airway Pressure ("BiPAP") therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP therapy is distinguishable from CPAP therapy, however, because Bi-Level PAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. Bi-Level PAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

III. Mechanical Ventilation:

46. Mechanical ventilation is a treatment to help a person breathe when they find it difficult or are unable to breathe on their own. A mechanical ventilator pushes airflow into the patient's lungs to help them breathe. Mechanical ventilation may be invasive ventilation with a tube inserted into the patient's airway, performed in the intensive care unit in the hospital or a long-term institutional setting. Non-invasive ventilation can be used at home by people with respiratory difficulties.

FACTUAL ALLEGATIONS

A. Background on Positive Airway Pressure Devices and Mechanical Ventilators.

47. BiPAP and CPAP devices, as well as mechanical ventilators, are medical devices designed to help patients breathe. BiPAP and CPAP devices are types of positive airway pressure ("PAP") devices typically used to treat OSA.

48. OSA is a breathing disorder characterized by repeating episodes of breathing cessation due to upper airway collapse during sleep. The episodes of breathing cessation are called "apneas," which can result in snoring, daytime sleepiness, and fatigue, but also increased risk of severe cardiovascular conditions, such as coronary artery disease, congestive heart failure, stroke, and sudden cardiac death.

49. CPAP devices work by delivering a continuous stream of filtered and pressurized air into a patient's airway, using a motor to draw room-temperature air through a filter and force the filtered air into a flexible tube attached to a mask covering the patient's nose or mouth. The continuous stream of filtered and pressurized air holds the airway open and prevents it from collapsing during sleep.

50. BiPAP devices are a common alternative to CPAP devices, and use two different pressures to hold the airway open during inhalation and exhalation.

51. Patients who use PAP devices to treat OSA typically use them every night while sleeping.

52. Ventilators are medical devices that take on the work of breathing when a patient suffers respiratory failure or is unable to breathe enough on their own, such as during surgery.

53. Respiratory failure is a serious condition that develops when the lungs cannot get enough oxygen into the blood resulting in a buildup of carbon dioxide that can damage tissues and organs and further impair oxygenation of the blood.

54. Many underlying conditions can cause respiratory failure, such as physical trauma, pneumonia, sepsis, drug overdose, or COVID-19, and if not treated appropriately, respiratory failure can lead to death.

55. Ventilators work by applying positive pressure to the airway through an

endotracheal tube, tracheostomy tube, or breathing mask, and blow air into the lungs. Patients usually exhale the air on their own, but sometimes the ventilator does it for them.

56. Some patients require ventilators for short periods of time, such as during surgery and under anesthesia, while other patients must use ventilators for longer periods of time or even the rest of their lives.

B. Rapid Growth of the OSA Treatment Industry.

57. OSA treatment is a multi-billion-dollar global industry dominated by the North American market, specifically the United States. In 2020, the global OSA device market was valued at $3.7 billion; the North American market accounted for a revenue share of 49.0%.[6] Moreover, within the North American market, the United States alone accounted for a revenue share of 91%.[7]

58. Likewise, the ventilator market represents another multi-billion-dollar industry. In 2020, the global ventilator market size was valued at $7.2 billion and is expected to grow at a compound annual rate of 4.9% from 2021 to 2028. North America dominates the ventilator market as well, accounting for a revenue share of 60% in 2020.[8]

59. Philips is a major manufacturer of PAP devices and ventilators, among other products, and earns substantial revenue from the research, development, design, manufacture, sale, distribution, and marketing of these devices.

60. According to Philips's 2020 Annual Report, "Sleep & Respiratory Care"

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[6] Sleep Apnea Devices Market Size, Share & Trends Analysis Report By Product Type (Diagnostic Devices, Therapeutic Devices, Sleep Apnea Masks), By Region (North America, Europe, APAC, Latin America, MEA), And Segment Forecasts, 2021 – 2028, https://www.grandviewresearch.com/industry-analysis/sleep-apnea-devices-market (last accessed September 2, 2021).

[7] Sleep Apnea Devices Market Size By Product (Therapeutics {Airway Clearance System, Adaptive Servo-ventilation {ASV}, Positive Airway Pressure {PAP} Device, Oral Appliances, Oxygen Devices}, Diagnostics {Actigraphy Systems, Polysomnography {PSG} Device, Respiratory Polygraph, Sleep Screening Devices}), By End-use (Home Care Settings & Individuals, Sleep Laboratories & Hospitals), COVID19 Impact Analysis, Regional Outlook, Application Potential, Price Trends, Competitive Market Share & Forecast, 2021 – 2027, https://www.gminsights.com/industry-analysis/sleep-apnea-devices-market-report (last accessed September 2, 2021).

[8] Mechanical Ventilator Market Size, Share & Trends Analysis Report, By Product (Critical care, Neonatal, Transport and Portable), By Region (North America, Europe, APAC, Latin America, MEA), And Segment Forecasts, 2021 – 2028, https://www.grandviewresearch.com/industry¬analysis/mechanical-ventilators-market (last accessed September 2, 2021).

constituted approximately 49% of Philips's total sales in its Connected Care line of business, which accounted for 28% of Philips's overall sales of about €19.535 billion ($23.735 billion).[9] [10]

61. The basic technology used in PAP devices today was originally developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who first used it to treat dogs with respiratory problems before the technology was adapted to humans.

62. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its own CPAP device in 1989.

63. These first-generation PAP devices created a new and commercially viable field of respiratory therapy. However, the devices themselves were large and noisy, resulting in an "arms-race" between competing manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and, most importantly, quieter.

64. The noise level of PAP devices became a driver of adult consumer preference, because loud devices interrupt the peaceful sleep of both the patient and their partner, making it less likely the patient will regularly use the device.

65. The issue of noise is also a particular problem in neonatal intensive care units (NICUs) where infants may remain on ventilators or PAP devices for long periods of time. As a result, hospitals also prefer quieter devices to protect the hearing of infants in the NICU.

66. Determined to develop the quietest devices on the market with the lowest possible decibel rating, device manufacturers, such as Philips, filled PAP and ventilator devices with sound abating foam to reduce the noise emitted from the motor and airflow.

67. Since 2009, Philips has incorporated PE-PUR foam in its PAP devices and

[9] U.S. dollar equivalence is based on the average EUR/USD exchange rate on January 25, 2021 when Philips announced its 2020 Fourth Quarter and Annual Results (1 EUR = 1.215 USD).
[10] PHILIPS, ANNUAL REPORT 2020 (2021).

ventilators, including the subject devices, for sound abatement purposes.

68. However, PE-PUR foam can degrade into particles and off-gas certain chemicals.

69. This process PE-PUR foam degradation is caused or exacerbated by environmental factors, such as heat, humidity, or moisture.

70. The particulates and off-gas chemicals resulting from the degradation of PE-PUR foam are toxic and cause both short-term and long-term health risks.

71. Nevertheless, owing to the design of Philips's PAP devices and ventilators, including the subject devices, forced air passes through potentially degraded PE-PUR foam before it is pumped into the patient's airway, thus exposing users to these toxins.

C. FDA 510(k) Clearance Process.

72. For decades, medical device manufacturers, including Philips, have used the 510(k)-clearance process to market PAP devices and ventilators in the United States.

73. The 510(k)-clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 ("MDA") of the Federal Food, Drug and Cosmetic Act.

74. Under this process, device manufacturers are only required to notify FDA at least ninety (90) days before marketing a device claimed to be "substantially equivalent" to a device FDA approved for sale prior to 1976, when the MDA was enacted.

75. Under Section 510(k) of the Federal Food, Drug and Cosmetic Act, a medical device does not have to go through the rigors of a clinical study to gain approval by FDA.

76. Subsequent amendments to the MDA allowed for 510(k) clearance of products deemed "substantially equivalent" to post-MDA 510(k) cleared devices.

77. Through this domino effect, medical devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by FDA prior

to 1976 could be sold to patients in a matter of ninety (90) days without any clinical testing demonstrating the device's efficacy or safety.

78. Clearance for sale under the 510(k) process does not equate to "FDA approval" of the cleared device.

79. In 2012, at the request of FDA, National Institute of Health ("NIH") conducted a thorough review of the 510(k) process, coming to the major conclusion that this process was not intended to ensure the safety of medical devices, stating:

> The 510(k)-clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.[11]

80. NIH explained, "[t]he assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'"[12]

81. Further, the NIH pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices ... [t]hus, it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."[13]

82. Philips utilized the 510(k)-clearance process for the recalled devices, including

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[11] Institute of Medicine (U.S.). Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process, Medical Devices and the Public's Health 189 (Institute of Medicine, 2011).
[12] Id. at 6.
[13] Id. at 5.

the subject devices.

83. Philips's System One received 510(k) clearance on January 29, 2002, and Philips's DreamStation received 510(k) clearance on October 18, 2013.

D. Life-Threatening Risks Result in a Massive Recall.

84. In April 13, 2021, Philips announced the launch of the DreamStation 2, the latest generation of Philips's flagship BiPAP/CPAP product family known as the "DreamStation."

85. Less than two weeks later, on April 26, 2021, Philips released its 2021 Q1 Quarterly Report, which included a regulatory update that warned its investors of "possible risks to users related to the sound abatement foam used in certain of Philips's sleep and respiratory care devices currently in use." The update nevertheless assured shareholders that Philips's upcoming and latest generation device, DreamStation 2, was not affected.[14]

86. On June 14, 2021, Philips announced an official world-wide recall of certain BiPAP and CPAP devices and ventilators that incorporated PE-PUR foam and pose life-threatening health risks to users:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, [**] and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification [*] to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.[15]

[14] PHILIPS, Q1 2021 QUARTERLY REPORT (2021).

[15] Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices, https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html (last visited Sept. 9, 2021).

87. The recall notification identified the following devices, including the subject devices, as affected by the recall:

a. **CPAP and BiPAP Devices:**

Continuous Ventilator, Non-life Supporting
1. DreamStation ASV;
2. DreamStation ST, AVAPS;
3. SystemOne ASV4;
4. C-Series ASV, S/T, AVAPS;
5. OmniLab Advanced+;

Non-continuous Ventilator
6. SystemOne Q series;
7. DreamStation CPAP, AutoCPAP, BiPAP;
8. DreamStation Go CPAP, APAP;
9. Dorma 400, 500 CPAP;
10. REMStar SE AutoCPAP;

Continuous Ventilator, Minimum Ventilatory Support, Facility Use Device:
11. E30.[16]

b. **Ventilators:**

Continuous Ventilator
1. Trilogy 100;
2. Trilogy 200;
3. Garbin Plus, Aeris, LifeVent Ventilator;

Continuous Ventilator, Minimum Ventilatory Support, Facility Use
4. A-Series BiPAP Hybrid A30;
5. A-Series BiPAP V30 Auto;

Continuous Ventilator, Non-life Supporting
6. A-Series BiPAP A40;
7. A-Series BiPAP A30.

88. The recall notification further admitted that degradation of the PE-PUR foam in the recalled devices exposes users to toxic and carcinogenic foam particulates and VOC emissions and poses the following critical safety risks:

[16] The E30 ventilator did not receive 510(k)-clearance, but rather FDA Emergency Use Authorization as a result of the COVID-19 pandemic.

> The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects.[17]

89. On the same date, Philips further issued a separate notice directed to health care providers, which warned that PE-PUR foam degradation "could result in a wide range of potential patient impact," including "serious injury which can be life-threatening," "permanent impairment," or "require medical intervention to preclude permanent impairment."[18] The notice to health care providers detailed two types of health hazards arising from PE-PUR foam degradation: ingestion or inhalation of toxic particulates and VOCs.

90. Philips disclosed that it "received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)," which a user might ingest or inhale and that lab analysis revealed that even before the particulates appear, the degraded foam may generate harmful chemicals:

> Potential Hazard: Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine

[17] Philips issues recall notification* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices, supra note 5.

[18] Sleep and Respiratory Care update Clinical information for physicians, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-corporate/philips-clinical-information-for-physicians-and-providers.pdf (last visited Sept. 9, 2021).

- Toluene Diisocyanate
- Diethylene glycol[19]

91. Toluene diamine ("TDA") is classified by United States Environmental Protection Agency ("EPA") as a probable human carcinogen.[20] The EPA also determined that acute exposure to TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (e.g., asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.

92. Toluene diisocyanate ("TDI") is considered by National Institute for Occupational Safety and Health ("NIOSH") to be a potential human carcinogen.[21]

93. Diethylene glycol ("DEG") is a widely used solvent, but there is limited information about its toxicity in humans, despite its historical involvement in mass poisonings around the world. Famously, DEG caused the death of one-hundred (100) people across fifteen (15) states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act in 1938.[22]

94. Philips also explained that testing confirmed the presence of several harmful organic compounds that may off-gas from the degraded foam and cause adverse health effects:

> Potential Hazard: Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

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[19] Id.

[20] Toluene-2, 4-Diamine, United States Environmental Protection Agency (January 2000), https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf

[21] Centers for Disease Control and Prevention, The National Institute of Occupational Safety and Health (NIOSH), https://www.cdc.gov/niosh/npg/npgd0621.html (last visited Sept. 9, 2021).

[22] Sulfanilamide Disaster, U.S. Food & Drug Administration, FDA Consumer Magazine (June 1981), https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf

- Dimethyl Diazene

- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)[23]

95. Philips admitted that these VOCs "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve," may cause "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," and may cause "adverse effects to other organs such as kidney and liver."

96. Also, on June 14, 2021, Philips's main competitor, ResMed, issued "[a] message from ResMed's CEO" to the public regarding the Philips recall. In this notice, ResMed CEO, Mick Farrell, stated that "ResMed devices are safe to use and are not subject to Philips' recall. ResMed devices use a different material than what Philips uses in their recalled machines."[24]

97. ResMed PAP devices and ventilators, in fact, use polyether urethane ("PEUR") or silicone-based foam for sound abatement purposes, not PE-PUR foam.

98. On June 30, 2021, FDA issued a Safety Communication alerting the public of the recall and the potential health risks from the PE-PUR sound abatement foam:

> The polyester-based polyurethane (PE-PUR) sound abatement foam, which is used to reduce sound and vibration in these affected devices, may break down and potentially enter the device's air pathway. If this occurs, black debris from the foam or certain chemicals released into the device's air pathway may be inhaled or swallowed by the person using the device.[25]

99. On July 8, 2021, Philips published an update to health care providers and stated

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[23] Id.

[24] Information regarding Philips' recall, https://www.resmed.com/en-us/other-manufacturer-recall¬2021/ (last visited Sept. 9, 2021).

[25] Philips Respironics CPAP, BiPAP, and Ventilator Recall: Frequently Asked Questions, https://www.fda.gov/medical-devices/safety-communications/philips-respironics-cpap-bipap-and-ventilator-recall-frequently-asked-questions (last visited Sept. 9, 2021).

that it had determined from a combination of user reports and lab testing that the degradation of the PE-PUR foam in the recalled devices was caused by "a process called hydrolysis" – i.e., the chemical breakdown of a compound due to a reaction with water. Philips further acknowledged that hydrolysis is the dominant source of degradation for PE-PUR foams, which has been well-established in scientific literature for many years.[26]

100. On July 29, 2021, FDA classified the Philips recall as a Class I recall, the most serious type of recall, which indicates that use of the recalled devices may cause serious injury or death resulting from the inhalation or ingestion of PE-PUR foam particles and off-gassed chemicals.[27]

E. Philips Knew the Risks, but Failed to Protect Consumers.

101. Philips knew about the potential health risks from its PAP devices related to PE-PUR foam degradation well before notifying the public on June 14, 2021.

102. Upon information and belief, Philips knew about the possibility of PE-PUR foam degradation since it began using this particular foam in its PAP devices.

103. Upon information and belief, Philips knew about the possibility of PE-PUR foam degradation since or before it began researching or developing the DreamStation 2 device.

104. Upon information and belief, Philips knew of the risk that degraded PE-PUR foam could produce toxic and carcinogenic particulates and VOC gas emissions.

105. Upon information and belief, Philips knew of the risk that incorporating PE-PUR foam in the air pathway of the subject device could result in users ingesting or inhaling toxic and carcinogenic particulates and VOC gas emissions.

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[26] Philips Sleep and Respiratory Care Update, Clinical Information, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/global-supplemental-clinical-information-document-070821-r6.pdf (last visited Nov. 11, 2021).

[27] Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication, https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks (last visited Sept. 9, 2021).

106. Philips should have known of the risk that degraded PE-PUR foam could produce toxic and carcinogenic particulates and VOC gas emissions, and that incorporating PE-PUR foam in the air pathway of the recalled devices could expose users to the risk of ingesting or inhaling toxic and carcinogenic particulates and VOC gas emissions.

107. An adverse event report from FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Respironics learned that a patient reported discovering "black dust" on her nose when she awoke the morning after using a RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."

108. Philips investigated this report, and confirmed the device contained "evidence of an unk[nown] black substance in the air path and on internal components...present throughout both the intake and exhaust portions of the air path..."[28]

109. Philips, however, denied that the presence of the black substance was due to a product defect.[29]

110. Other consumers have also complained about black particles in Philips's devices several years prior to the 2021 recall, as evidenced by forum posts and statements on internet message boards frequented by OSA patients.

111. In 2018, the user "trickyneedsleep" reported on apneaboard.com that the filters of his DreamStation Auto turned black within three (3) days of use.[30]

112. In 2019, the user "WSHenry" reported on apneaboard.com in a thread entitled "DreamStation Filter Contamination" that "both the pollen and ultra-fine filters in my machine

[28]MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=2000987&p c=BZD (last visited Sept. 10, 2021).
[29] Id.
[30] Trickyneedsleep, Dirty filters, APNEA BOARD (Sept. 14, 2018, 5:12 AM), http://www.apneaboard.com/forums/Thread-Dirty-filters.

were clogged with black (Carbon?) particles."[31] The user further noted that the "water chamber was completely dry. There were odd odors noted, and the water chamber was undamaged." He explained that he had recently cleaned the filters and that "[t]here was only a small amount of dust on the furniture, and the machine and tubing is clean. I do not burn candles nearby, and the furnace is off. I do have the window slightly opened, as is the case nearly year-round." The user asked: "Is it possible the contamination is from the blower?"

113. In 2019, the user "Skogcat1" reported on apneaboard.com in a thread entitled "Black sticky dust in CPAP machine" that, when using the REMStar Auto, there were "sticky black dust particles" in the humidifier chamber.[32]

114. In June 2021, shortly after the recall was announced, on a Reddit thread entitled "Dreamstation Foam," user "BOSSHOG999" posted: "I was wondering what the hell those black particles were in my tube."[33]

115. Philips, like most companies, monitored message boards, such as apneaboard.com and reddit.com, and social media networks, such as Facebook, and therefore received notice about the potential for PE-PUR foam degradation in the subject devices and black particles in the machines since shortly after launch, if not earlier.

F. Plaintiff Developed Breathing Disorders, Dizziness, Extreme Nausea, Headaches and Loss of Balance (Falling) from the Use of Defendants' CPAP Devices.

116. On or about October 202, Plaintiff was diagnosed with obstructive sleep apnea by his physician, Jon Floriano, MD of Middlefield, Ohio.

117. Plaintiff's use of the subject devices caused the development and progression of

[31] WSHenry, DreamStation Filter Contamination, APNEA BOARD (July 1, 2019, 11:52 AM), http://www.apneaboard.com/forums/Thread-DreamStation-Filter-Contamination.
[32] Skogcat1, Black sticky dust in CPAP machine, APNEA BOARD (Jan. 22, 2019, 3:33 PM), http://www.apneaboard.com/forums/Thread-Equipment-Black-sticky-dust-in-CPAP-machine
[33] BOSSHOG999, Dreamstation Foam, REDDIT, R/CPAP (July 2021) https://www.reddit.com/r/CPAP/comments/o0vncx/dreamstation foam/

his illnesses.

118. Plaintiff's development and progression of his illnesses, as a result of his use of the subject devices, necessitated treatment resulting in adverse effects, limitations, and sequelae, as well as the need for continuous future medical care and treatment.

119. Plaintiff's development and progression of his illnesses, resulting treatment, and need for future medical care and treatment would not have occurred but for the defective nature of the subject devices and Philips's wrongful conduct.

120. Due to the defective nature of the subject devices and Philips's wrongful conduct, Plaintiff has suffered severe injuries and permanent limitations, has undergone significant treatment, and will be required to undergo significant treatment in the future.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

121. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff and his physicians the true risks associated with the subject devices.

122. As a result of Philips's actions, Plaintiff was unaware, and could not have reasonably known or learned through reasonable diligence, that she had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Philips's acts and omissions.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY-FAILURE TO WARN

123. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in

this Complaint with the same force and effect as if fully set forth herein.

124. At all relevant times, Philips engaged in the business of researching, developing, designing, manufacturing, selling, distributing, and marketing the recalled devices, including the subject devices, which are defective and unreasonable dangerous to consumers, including Plaintiff, because they do not contain adequate warnings or instructions concerning their dangerous characteristics.

125. At the time Philips researched, developed, designed, manufactured, sold, distributed, marketed, and otherwise released the subject devices into the stream of commerce, Philips knew or should have known that the recalled devices, including the subject devices, presented an unreasonable danger to users when used as intended and in a reasonably anticipated manner.

126. Specifically, at all relevant times, Philips knew, or should have known, that the recalled devices, including the subject devices, pose a significant health risk in that the PE-PUR sound abatement foam incorporated in the devices may break down and release toxic particles or chemical emissions into a device's air pathway, which a person may ingest or inhale resulting in significant injuries.

127. At all relevant times, Philips knew, or should have known, that the subject devices created significant risks of serious bodily harm to consumers and Plaintiff, as alleged herein, and Defendants failed to adequately warn reasonably foreseeable users and their health care providers, such as Plaintiff, his physician, and health care providers, of the inherent risks of toxic exposure resulting in significant and life-threatening injuries, such as lung diseases and cancer, associated with use of the subject devices.

128. At all relevant times, Philips had a duty to properly research, develop, design,

manufacture, sell, distribute, and market the subject devices, which included providing proper warnings, and taking such steps as necessary to ensure the subject devices did not cause users, like Plaintiff, to suffer from unreasonable and dangerous risks.

129. Philips, as a researcher, developer, designer, manufacturer, seller, distributor, and marketer of medical devices, is held to the knowledge of an expert in the field, and had a continuing duty to warn users, including Plaintiff, of the risks associated with using the subject devices.

130. Philips had a duty to warn Plaintiff and other consumers of the risks of harm resulting from exposure to degraded PE-PUR foam, its particulates and chemical emissions as a result of using the subject devices.

131. These risks are of such a latent nature that health care providers and users could not have recognized the potential harm without proper warnings provided by Philips.

132. At all relevant times, Philips could have provided proper warnings or instructions regarding the full and complete risks of the subject devices, because Philips knew, or should have known, of the unreasonable risks of harm associated with the use of, or exposure to, the subject devices.

133. At all relevant times, Philips failed and deliberately refused to investigate, study, test, promote the safety, or minimize the dangers to those would foreseeably use or be harmed by the subject devices, including Plaintiff.

134. Plaintiff used and was exposed to the subject devices without knowledge of their dangerous characteristics.

135. Despite Philips's obligation to unilaterally strengthen the warnings, Philips instead actively concealed knowledge of the true risks concerning use of the subject devices and

degradation of the PE-PUR foam incorporated in the devices.

136. At all relevant times, Plaintiff used or was exposed to the subject devices while using them for their intended or reasonably foreseeable purpose, without knowledge of their dangerous characteristics.

137. Plaintiff could not have reasonably discovered the defects and risks associated with the subject devices prior to or at the time of using it, and relied upon the skill, superior knowledge, and judgment of Philips to know about and disclose those serious health risks associated with using the subject devices.

138. Philips knew or should have known that failing to disseminate warnings or instructions regarding the risk of exposure to degraded PE-PUR foam or the dangers of toxic exposure causing severe and life-threatening injuries, such as lung diseases and cancer, rendered the subject devices dangerous and unfit for their ordinary, intended, and reasonably foreseeable use.

139. The information Philips did provide or communicate entirely failed to contain relevant or adequate warnings or precautions that would have enabled consumers, such as Plaintiff, to use the subject devices safely.

140. Instead, Philips failed to disseminate any information regarding the true and complete risks and otherwise disseminated information that was inaccurate, incomplete, false, and misleading, and which failed to communicate accurately or adequately the risk of injury with use of the subject devices.

141. In fact, even after April 26, 2021, when Philips first suggested to its shareholders that its PAP devices and ventilators might contain a serious health hazard, it continued to sell those devices, without providing consumers with further or complete warnings, until the date of

the eventual recall on June 14, 2021, and during that time, continued to promote its next generation devices that were not subject to the same health hazards.

142. Philips knew or should have known of the unreasonable risks from use of the subject devices, and downplayed or otherwise suppressed any information or research about the risks and dangers of the subject devices.

143. Philips was able, and in accordance with federal law, to disclose the known risks associated with the subject devices through public service announcements, promotions, advertisements, and other public information sources as it did in its communications to shareholders and ultimately has done since announcing the recall on June 14, 2021.

144. Philips is liable to Plaintiff for injuries caused by its negligent or willful failure to provide adequate warnings, instructions, or relevant information and data regarding the risks associated with using the subject devices.

145. Had Philips provided adequate warnings, instructions, or relevant information, and disseminated the risks associated with the subject devices, Plaintiff could have obtained or used alternative devices for the treatment of OSA and avoided the risk of the development and progression of lung diseases and cancer.

146. As a direct and proximate result of Philips placing the defective subject devices into the stream of commerce, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT II
STRICT LIABILITY-DESIGN DEFECT

147. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

148. The subject devices are inherently dangerous and defective, unfit and unsafe for their intended uses and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

149. The design of the subject devices, including, but not limited to, the design incorporating the use of PE-PUR foam and the placement of this foam within the air pathway of the subject devices, was unreasonably dangerous and defective, resulting in the ingestion and inhalation of degraded PE-PUR foam particulates and chemical emissions.

150. The ingestion and inhalation of these particulate and chemical emissions is known to cause headaches, irritation, inflammation, respiratory issues, and toxic and carcinogenic effects, including the development of lung diseases and cancer.

151. The subject devices used by Plaintiff were defective in design, in that their risk of harm exceeded any claimed benefits.

152. The subject devices did not perform as an ordinary consumer would expect.

153. The inherent risks, hazards, and dangers associated with the design of the subject devices, incorporating PE-PUR foam in such a manner that exposes the user, such as Plaintiff, to the ingestion or inhalation of degraded PE-PUR foam particulates or chemical emissions rendered the subject devices unreasonably dangerous.

154. Accordingly, the design of the subject devices rendered them not reasonably fit, suitable, or safe for their intended purpose.

155. Neither Plaintiff, nor his physicians or healthcare providers could have, by the

exercise of reasonable care, discovered the subject devices' defective conditions or perceived their unreasonable dangers prior to him using the subject devices.

156. There are other similar CPAP devices that incorporate PE-PUR foam for sound abatement purposes, but do not result in the ingestion or inhalation of toxic foam particulates or chemical emissions.

157. Furthermore, there are other similar CPAP devices that do not incorporate PE-PUR foam that is subject to degradation or result in exposure to the user of toxic particulates, chemical emissions, or other harmful compounds.

158. Safer, alternative devices from other manufacturers were available that did not suffer from the defects as set forth herein and that did not have an unreasonable risk of harm as with the subject devices and their unsafe incorporation of PE-PUR foam.

159. As a result of the foregoing design defects, Philips created risks to the health and safety of its users, including Plaintiff, that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the subject devices.

160. The risk-benefit profile of the subject devices are unreasonable, and they should have had stronger and clearer warnings, or should not have been sold in the market.

161. Philips intentionally or recklessly designed the subject devices with wanton and willful disregard for the rights and health of Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

162. As a proximate result of Philips's design of the subject devices, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT III
NEGLIGENT FAILURE TO WARN

163. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

164. Philips owed Plaintiff a duty of care to warn of any risks associated with the subject devices.

165. Philips knew or should have known of the true risks associated with the subject devices, but failed to warn Plaintiff, his physician, and health care providers.

166. Philips's negligent breach of their duty to warn caused Plaintiff to sustain serious and permanent injuries, including the development of lung diseases and other illnesses.

167. Plaintiff would not have purchased, chosen, or paid for the subject devices if she knew of the defects and the risks associated with the use of the subject devices.

168. As a proximate result of the Philips's negligent failure to warn of the risks associated with use of the subject devices, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT IV
NEGLIGENT DESIGN DEFECT

169. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

170. At all relevant times, Philips researched, developed, designed, manufactured, sold, distributed, and promoted the subject devices in the regular course of business.

171. The subject devices were designed and intended to be used for the treatment of OSA.

172. Philips knew or by the exercise of reasonable care, should have known, that use of the subject devices, as a result of their defective design, was dangerous, harmful and injurious when used by Plaintiff in a reasonably foreseeable manner.

173. Philips had a duty to exercise reasonable care in designing the subject devices in such a manner that they were not dangerous, harmful, injurious or pose an unreasonable risk to consumers, such as Plaintiff.

174. Philips breached its duty by failing to use reasonable care in the design of the subject devices by designing the devices such that PE-PUR foam incorporated in the devices could produce highly harmful particulates and chemical emissions that enter the devices' air pathway, which a user, such as Plaintiff, may then ingest or inhale.

175. The subject devices contained and produced toxic particulates and chemical emission from degraded PE-PUR foam that can lead to short-term and long-term health risks, including, headaches; irritation of the skin, eye, and respiratory tract; respiratory distress; asthma; inflammation; nausea; vomiting; and lung diseases and cancer, all of which Philips knew or should have known could result from use of the subject devices, thereby rendering the devices not reasonably fit, suitable, or safe for their intended purpose.

176. Philips breached its duty when it failed to use commercially feasible alternative designs to minimize the above-mentioned harms, including, but not limited to designing products that prevented exposure to particulates and chemical emissions from PE-PUR foam.

177. The dangers of the subject devices outweighed the benefits and rendered the device unreasonably dangerous.

178. There are other similar devices that do not incorporate PE-PUR foam in such a manner that is subject to degradation.

179. There are other similar devices that incorporate PE-PUR foam in such a manner that the user does not ingest or inhale degraded foam particulates or chemical emission.

180. Safer, alternative devices from other manufactures were available that did not have an unreasonable risk of harm as with the subject devices.

181. The risk-benefit profile of the subject devices was unreasonable, and should have had stronger and clearer warnings, or should not have been sold in the market.

182. As a proximate result of the Philips's negligent design of the subject devices, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants jointly and severally for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT V
BREACH OF EXPRESS WARRANTY

183. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

184. At all relevant times, Philips intended that the subject devices be used in the

manner that Plaintiff in fact used them, and expressly warranted that each was safe and fit for use by Plaintiff, that they were of merchantable quality, that their risks were minimal and comparable to other comparable or substantially similar devices, and that they were adequately tested and fit for their intended use.

185. At all relevant times, Philips was aware that consumers, including Plaintiff, would use the recalled devices, including the subject devices, and as a result are in privity with Philips.

186. The subject devices were expected to reach and did in fact reach Plaintiff without substantial change in the condition in which they were manufactured and sold by Philips.

187. Philips warranted the subject devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

188. Philips breached this express warranty upon the sale and distribution of the subject devices.

189. At the point of sale, the subject devices while appearing normal—contained immediate latent defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

190. In reliance upon Philips's express warranty, Plaintiff used the subject devices as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Philips.

191. At the time of making such express warranties, Philips knew or should have known that the subject devices were not safe and had numerous defects, many of which Philips did not accurately warn about, thus making the subject devices unreasonably unsafe for their intended purpose.

192. Members of the medical community, including physicians and other health care providers, as well as Plaintiff, his physicians, and health care providers, relied upon the representations and warranties of Philips in connection with the use, recommendation, description, or prescribing of the subject devices.

193. Had Plaintiff known the subject devices were unsafe for use, she would not have purchased or used them.

194. Plaintiff reasonably expected, at the time of purchase, that the subject devices were safe for their ordinary and intended use.

195. Philips breached its express warranties to Plaintiff in that the subject device was not of merchantable quality, safe, and fit for their intended uses, nor were they adequately tested.

196. Philips breached its express warranties to Plaintiff in violation of applicable state statutes and common law, by manufacturing, marketing, and selling the subject devices to Plaintiff and causing damages as will be established at trial.

197. As a proximate result of the Philips's breach of express warranty, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants jointly and severally for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT VI
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

198. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

199. Philips knew of the intended use of the subject devices at the time it researched,

developed, designed, manufactured, sold, distributed, and promoted the subject devices for use by Plaintiff, and impliedly warranted the subject devices to be of merchantable quality and safe and fit for their ordinary and intended use.

200. Plaintiff, his physicians, and health care providers were, at all relevant times, in privity with Philips.

201. The subject devices were expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in their condition in which they were manufactured and sold by Philips.

202. Philips impliedly warranted that the subject devices were merchantable pursuant to UCC § 2-314 and suitable for the ordinary purpose for which they were intended to be used.

203. Philips's representations and implied warranties were false, misleading, and inaccurate because the subject devices were defective, and not of merchantable quality.

204. Philips breached the implied warranty of merchantability in connection with the sale and distribution of the subject devices.

205. At the point of sale, the subject devices, while appearing normal, contained defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

206. At the time the subject devices were researched, developed, designed, manufactured, sold, distributed, and promoted by Philips, Philips knew of the use for which they were intended and impliedly warranted the subject devices to be of merchantable quality and safe and fit for such use.

207. Plaintiff reasonably expected, at the time of purchase, that the subject devices were safe for their ordinary and intended use.

208. Had Plaintiff known the subject devices were unsafe for use and not of

merchantable quality, she would not have purchased or used them.

209. As a proximate result of the Philips's breach of implied warranty, Plaintiff was injured and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against Defendants jointly and severally for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT VII
PUNITIVE DAMAGES

210. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

211. Philips knew or should have known that the subject devices were inherently dangerous with respect to the risk of PE-PUR foam degradation causing exposure to toxic particulates, chemical emissions, or other compounds resulting in harmful and carcinogenic effects, including lung diseases and cancer.

212. Philips knew or should have known that the subject devices were inherently more dangerous with respect to the aforesaid risks than alternative devices on the market.

213. Philips attempted to and did misrepresent facts concerning the risks and safety of the subject devices.

214. Philips's misrepresentations included knowingly withholding material information concerning the safety of the subject devices from the medical community and patients, including Plaintiff, his physicians, and health care providers.

215. Philips knew and recklessly disregarded the fact that use of the subject devices for their intended purposes could result in toxic exposure resulting in harmful and carcinogenic

effects.

216. Notwithstanding the foregoing, Philips marketed the subject devices without disclosing the aforesaid health and safety risks when there were safer alternative devices that did not pose the same or similar health and safety risks.

217. Philips knew the defective and unreasonably dangerous nature of the subject devices, but continued to research, develop, design, manufacture, sell, distribute, and market the subject devices in conscious, reckless, or negligent disregard of the foreseeable harm in order to maximize sales and profits at the expense of the health and safety of patients, including Plaintiff.

218. Philips's intentional, reckless, fraudulent, and malicious failure to disclose information regarding the health and safety risks of the subject devices deprived Plaintiff, his physicians, and health care providers the necessary information to enable them to weigh the true risks of using the subject devices against their benefits.

219. As a direct and proximate result of Philip's conscious and deliberate disregard for the rights and safety of patients, Plaintiff suffered severe personal injuries and sustained damages and pecuniary loss in a sum exceeding the jurisdictional minimum of this Court in an amount to be determined at trial.

220. The aforesaid conduct of Philips was committed with knowing, conscious, and deliberate disregard for the rights and safety of patients, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Philips and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants jointly and severally for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and such other relief as this Court deems just and proper.

COUNT VIII
LOSS OF CONSORTIUM

221. Plaintiff Janet Kravetz incorporates by reference each allegation set forth in the preceding paragraphs as if fully stated herein.

222. At all times herein mentioned, Plaintiff Janet Kravetz was and remains the lawful spouse of Plaintiff John Kravetz.

223. As a direct, legal and proximate result of the culpability and fault of each of the defendants, Plaintiff Janet Kravetz has suffered a loss of consortium and has been deprived of the society, companionship, comfort, love, solace, and assistance of Plaintiff John Kravetz, who was exposed to the defendants' defective devices as described above, and further that said loss is the direct and proximate result of the acts and/or omissions of the defendants as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all relief as this Court deems just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants jointly and severally for damages to which he is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, including:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future fraudulent practices;
c. pre-judgment and post-judgment interest;
d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
e. any other relief the Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all triable issues within this pleading.

Dated: January 5, 2022

Respectfully submitted,

KELLEY & FERRARO, LLP

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